

AMENDMENT UNDER 37 C.F.R. §1.111

U.S. Application 09/509,677

AI  
Amended  
Sub 2  
cont'd

magnesium chloride and the like. Among them L-menthol is particularly desirable, because it exerts a refreshing feeling and further increases the bitterness-improving effect. L-Menthol is added in an amount of from 0.01 to 2% by weight, preferably from 0.05 to 1% by weight, more preferably from 0.1 to 0.5% by weight, based on the total weight of the preparation.

**IN THE CLAIMS:**

**Please cancel claim 2 without prejudice or disclaimer.**

**Please enter the following amended claims:**

A2

1. (Amended) A taste masking oral administration preparation consisting essentially of a drug having at least one basic group in its structure, thereby rendering an unpleasant taste, a sugar alcohol having a heat of dissolution of -20 cal/g or less and a pH adjusting agent.

A3

3. (Amended) The oral administration preparation according to claim 1, wherein the drug has a bitter taste.

4. (Amended) The oral administration preparation according to claim 1, wherein the drug is an H<sub>2</sub> blocker.

A4

6. (Amended) The oral administration preparation according to claim 1, wherein the drug is a mixture of one or more compounds selected from the group consisting of cimetidine, tranexamic acid and cetraxate hydrochloride.

7. (Amended) The oral administration preparation according to claim 1, wherein the sugar alcohol having a heat of dissolution of -20 cal/g or less is a mixture of one or more compounds selected from the group consisting of erythritol, xylitol, mannitol and sorbitol.

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8. (Amended) The oral administration preparation according to claim 1, wherein the sugar alcohol having a heat of dissolution of -20 cal/g or less is erythritol.

9. (Amended) The oral administration preparation according to claim 1, wherein the sugar alcohol having a heat of dissolution of -20 cal/g or less is from 0.1 to 50 parts by weight based on 1 part by weight of the drug having an unpleasant taste.

10. (Amended) The oral administration preparation according to claim 1, wherein the sugar alcohol having a heat of dissolution of -20 cal/g or less is from 5 to 10 parts by weight based on 1 part by weight of the drug.

11. (Amended) The oral administration preparation according to claim 1, wherein pH value of a 1% (w/v) aqueous solution or 1% (w/v) aqueous suspension of the pH adjusting agent is equal to or higher than the pKa value of the drug or equal to or higher than the pH value of a 1% (w/v) aqueous solution or 1% (w/v) aqueous suspension of the drug.

12. (Amended) The oral administration preparation according to claim 1, wherein the pH adjusting agent is a mixture of one or more compounds selected from the group consisting of sodium bicarbonate, sodium dihydrogen phosphate anhydrous and precipitated calcium carbonate.

13. (Amended) The oral administration preparation according to claim 1, wherein the pH adjusting agent is from 0.1 to 200 parts by weight based on 1 part by weight of the drug.

14. (Amended) The oral administration preparation according to claim 1, wherein the pH adjusting agent is from 0.5 to 7 parts by weight based on 1 part by weight of the drug.

15. (Amended) A taste masking oral administration preparation consisting essentially of an H<sub>2</sub> blocker, from 5 to 10 parts by weight of a sugar alcohol having a heat of

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Original  
Sub B3  
dissolution of -20 cal/g or less and from 0.5 to 7 parts by weight of a pH adjusting agent, based on 1 part by weight of an H<sub>2</sub> blocker.

16. (Amended) The oral administration preparation according to claim 1, wherein it further contains a sweetener and/or a corrective agent.

17. (Amended) The oral administration preparation according to claim 1, wherein it further contains aspartame and/or L-menthol.

Sub B1  
AS  
19. (Amended) A method for masking the taste of an oral administration preparation comprising administering an oral administration preparation consisting essentially of a drug having at least one basic group in its structure thereby rendering an unpleasant taste, which is effected by including a sugar alcohol having a heat of dissolution of -20 cal/g or less and a pH adjusting agent.

Sub B4  
20. (Amended) The method for masking the taste of an oral administration preparation according to claim 19, wherein a sweetener and/or corrective agent is further included.

**Please add the following new claims:**

AG  
21. (New) A method for masking the taste of an oral administration preparation in an oral cavity, comprising administering an oral administration preparation which comprises a drug compound which has a basic group in its structure, and increasing pH in the oral cavity to the pK<sub>a</sub> value or more of the drug using a pH adjusting agent in the oral administration preparation wherein the basic group is un-dissociated and wherein the solubility of the drug compound is reduced in the oral cavity.

22. (New) A method for masking the taste of an oral administration preparation in an oral cavity, comprising administering an oral administration preparation which comprises a drug compound which has a basic group in its structure and changing the taste of the drug by increasing its solubility in fat.

23. (New) A method for masking the taste of an oral administration preparation in an oral cavity, comprising

administering an oral administration preparation which comprises an amphoteric drug compound which has a basic and an acidic group in its structure,

increasing pH in the oral cavity to the pKa value or more of the acidic group in the structure using a pH adjusting agent in the oral administration preparation,

effecting dissociation of the acid group, and

forming an intramolecular salt or a salt of the pH adjusting agent.

24. (New) The method of claim 23 further comprising dissociation of the basic group.

25. (New) A method for masking the taste of an oral administration preparation in an oral cavity, comprising

administering an oral administration preparation which comprises a drug compound which is an acid addition salt of a compound which has a basic group or an acid addition salt of an amphoteric compound,

eliminating the acid addition salt and converting the drug into its free form using a pH adjusting agent in the oral administration preparation.